DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

T2090M

September 21, 1998

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 53

Michael J. Kuske
President
Innomedica, Inc.
7452 - 78th Street
Bloomington, Minnesota 55439

Dear Mr. Kuske:

During our recent inspection of your firm located in Bloomington, MN, our investigator determined your firm manufactures sterile pacemaker leads and adaptors. These pacemaker leads and adaptors are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage or installation are not in conformance with the Quality Systems Regulations of Title 21, Code of Federal Regulations, Part 820 (21 CFR 820), as follows:

* Failure to investigate possible product failures as complaints--a failure to follow your own Complaint standard operating procedures.

* Inadequate receiving inspection and failure to follow your own incoming inspection standard operating procedures.

* Inadequate corrective/preventive actions as noted by repeat product failures.

* Failure to conduct Medical Device Reporting evaluations associated with complaints and returned product, which is also counter to your own MDR standard operating procedures.

Please refer to the form FDA-483 issued on August 27, 1998, for a more complete listing of the violations noted during this investigation.

The above inspection revealed your devices may also be misbranded within the meaning of Section 502(t)(2) of the Act in that your firm failed to submit information to the Food and Drug Administration (FDA) as required by the Medical Device Reporting (MDR) regulations as specified in 21 CFR 803. Specifically, you failed to report an MDR to FDA after receiving information which reasonably suggested that one of your commercially distributed devices may have caused or contributed to a death.

This letter is not intended to be an all-inclusive list of the deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and the form FDA-483 issued at the close-out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending applications for pre-market approval (PMAs) or export approval requests will be approved, and no pre-market notifications [510(k)] will be found to be substantially equivalent for products manufactured at the facility in which the above violations were found until the violations have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food

and Drug Administration without further notice. These actions include but are not limited to product seizure, injunction and/or civil penalties against you and your firm.

Please notify this office within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to ensure that similar violations do not recur. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be directed to Compliance Officer Howard E. Manresa at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

TPN/ccl